

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-4 and 12 under 35 U.S.C. § 103(a) as unpatentable over Bartel, et al., (WO 97/31001; Reference N) (Paper No. 0222, pages 2-3). Applicants respectfully traverse.

To properly maintain a rejection under 35 U.S.C. § 103, three conditions must be met. First, the prior art must have suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the prior art must also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in the Applicant's disclosure. Finally, the prior art reference must teach or suggest all the claim limitations. See *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

The Examiner has stated that "It would have been obvious to one of ordinary skill to form a semihydrochloride from a monohydrochloride of the 8-cyano-1-cyclopropyl-7-(1S,6S-2,8diazabicyclo-[4,3,0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolnecarboxylic acid" (Paper No. 0222, pages 2-3).

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973, MPEP 2142.

As such, there is no suggestion in the reference to make the semihydrochloride of 8-cyano-1-cyclopropyl-7-(1S,6S-2,8diazabicyclo-[4,3,0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolnecarboxylic acid; and furthermore, the Examiner has not provided any explanation as to why it would have been obvious to one of ordinary skill to form a semihydrochloride from a monohydrochloride of the 8-cyano-1-cyclopropyl-7-(1S,6S-2,8diazabicyclo-[4,3,0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolnecarboxylic acid.

In addition, the prior art must provide one of ordinary skill in the art the motivation to make the proposed modification needed to arrive at the claimed compound. *In re Jones*, 21 USPQ2d 1941, 1941. In the instant case, the Examiner has not provided any evidence as to why one skilled in the art would have been motivated to modify the compounds disclosed in the cited reference to form a semihydrochloride.

The Examiner has also stated that "compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds" (Paper No. 0222, page 3).

If the Examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. § 103, the Examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. *In*

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re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992), MPEP 2142. When evidence of secondary considerations such as unexpected results is presented, the Examiner must evaluate the evidence (MPEP 2141). Furthermore, evidence that the compound possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). A decision to make a rejection in the face of all the evidence must show that it was based on the totality of the evidence.

As described on pages 4-5 of the specification, the hydrochloride of formula (IV) which is disclosed in Bartel, et al., demonstrated a solubility of 2.8% (w/w). Surprisingly, the semihydrochloride of the present invention exhibited a solubility of 19% (w/w); considerably more soluble than the hydrochloride disclosed in the prior art. Thus, unexpected results for the claimed compounds over those of the generic prior art compounds have been demonstrated. That is, Applicants have shown that the claimed invention exhibits a superior property (i.e., surprisingly high solubility) that a person of ordinary skill in the art would have found unexpected. Therefore, a result which would have been surprising to a person of ordinary skill would not have been obvious.

It is therefore respectfully submitted that Bartel, et al., (WO 97/31001) fail to teach or suggest the compounds as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references. Furthermore, Applicants have demonstrated unexpected results for the claimed compounds over those of the generic prior art compounds. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the present rejection, and Applicants submit that claims 1-4 and 12, and dependent claims 5-11 and 15-24, are in condition for allowance.

Claim Objections

The Examiner objected to claims 5-11 and 15-24 as being dependent upon a rejected base claim.

Based on the reply stated above, Applicants submit that claims 1-4 and 12 are in condition for allowance, and as such dependent claims 5-11 and 15-24 are also in condition for allowance.

It is submitted that Applicants have overcome the claim objections, and thus, claims 5-11 and 15-24 are allowable.

CONCLUSION

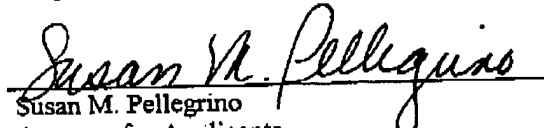
For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, and reconsideration and withdrawal of the present rejections and objections. Should there be any further matter requiring consideration, Examiner Robinson is invited to contact the undersigned counsel.

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If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,


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